PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/06 | A1

(11) International Publication Number: **WO 99/49808**

(43) International Publication Date: 7 October 1999 (07.10.99)

(21) International Application Number: PCT/IE99/00018

(22) International Filing Date: 31 March 1999 (31.03.99)

(30) Priority Data:
980235 31 March 1998 (31.03.98) IE

(71) Applicant *(for all designated States except US)*: SALVIAC LIMITED [IE/IE]; 39–40 Upper Mount Street, Dublin 2 (IE).

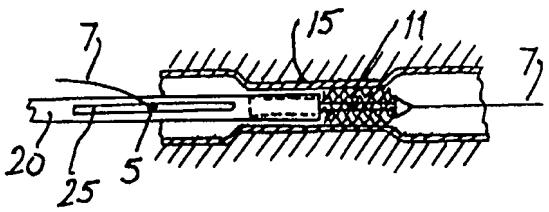
(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: GILSON, Paul [IE/IE]; Uggool, Moycullen, County Galway (IE). ROUBIN, Gary, Sidney [AU/US]; 145 East 81st Street, Penthouse B, New York, NY 10028 (US).

(74) Agents: O'BRIEN, John, A. et al.; John A O'Brien & Associates, 3rd floor, Duncairn House, 14 Carysfort Avenue, Blackrock, County Dublin (IE).

(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DE (Utility model), DK, DK (Utility model), EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: A DELIVERY CATHETER



(57) Abstract

A rapid exchange stent delivery catheter (1) for delivery and deployment of a stent (11) has a catheter shaft (2) having a guidewire lumen (4) defined by a passageway with an entrance (5) and an exit (6). The stent (11) is of a shape memory metallic alloy and is constrained by a sheath (20). The sheath (20) has an elongate slot (25) aligned with the guidewire lumen entrance (5) so that a guidewire (7) is not obstructed during movement of the sheath (20) to deploy the stent (11). The sheath (20) is pulled back linearly by a thumbscrew mechanism to deploy the stent (11).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

"A Delivery Catheter"

Introduction

The invention relates to a delivery system for delivery and deployment of a stent, to a desired vascular location.

Vascular intervention is today undertaken to treat a large number of diseases that had heretofore been treated by surgery. Stents are used widely in a number of applications to provide structural support to vessels that are being treated. Typically, a vascular intervention procedure is required to restore the flow of blood through an artery that has been constricted by a build up of atherosclerotic material. Medical practice has shown that implanting stents at the site of disease is effective. Various types of stents have been devised and the therapy is well known and widely practised.

Stent designs are broadly divided into two categories, balloon expandable stents and self-expanding stents. The invention relates particularly to the delivery and positioning of self-expanding stents. The term self-expanding refers to the inherent material properties of the stent which cause the expansion of the stent once an external constraint has been removed. The effect is most commonly achieved by using a shape memory metallic alloy such as nitinol.

Generally, stents are delivered to the desired location by means of a catheter, specifically referred to as a delivery catheter. Delivery catheters are threaded through a guiding catheter to the site of the disease and once the correct position has been established by means of fluoroscopic or other imaging method, the stent is deployed.

There is however a problem with conventional stent delivery systems in that it is difficult and time consuming to deploy stents. A full length over the wire catheter

is used in combination with an exchange length guidewire over which the delivery catheter is manipulated. Such systems are cumbersome to handle and a second operator is generally required to assist the lead clinician in controlling the procedure. When the guidewire is positioned at the commencement of the procedure, it is desirable that it's position is stable during the remainder of the procedure as it provides access to the treatment site for the therapeutic or diagnostic devices used in treatment. If it is desirous to insert or exchange a catheter, it is necessary to thread the catheter over the guidewire while retaining control of the guidewire. This is achievable only if the length of available guidewire outside the body is greater than the length of the catheter being loaded. Intravascular catheters typically measure 1.3 metres or more. It is impossible for one clinician to maintain position and control of a guidewire and simultaneously thread on a catheter more than a metre away.

There is therefore a need for a delivery catheter system which will overcome at least some of these difficulties.

Statements of Invention

According to the invention there is provided a stent delivery catheter for delivery and deployment of a stent comprising: -

an elongate catheter body;

a self-expanding stent overlying said catheter body at a distal end thereof;

a sheath overlying said stent to constrict the stent during delivery;

the catheter body having a guidewire lumen with a guidewire exit at a distal end of the catheter body and a guidewire entrance proximal of the stent;

a guidewire extending through the lumen between the guidewire entrance and the guidewire exit; and

stent deployment means comprising means for moving the sheath relative to the catheter body to release the stent;

the sheath having guidewire accommodating means for accommodating the guidewire so that the guidewire entrance is not obstructed during movement of the sheath relative to the catheter body.

Most preferably the guidewire accommodating means is an opening in the sheath which is arranged to align with the guidewire entrance to prevent obstruction of the entrance on deployment of the stent.

Preferably the guidewire accommodating means is configured to correspond with the operation of the stent deployment means.

In a preferred arrangement the sheath opening has a length which is greater than or equal to the length of the stent to be deployed.

Ideally the sheath opening comprises an elongate slot.

Preferably the stent deployment means is a linear actuating means. In a preferred arrangement the actuating means includes converter means for converting rotational movement of an actuator into linear motion to move the sheath linearly.

Preferably the converter means comprises a shuttle which is linearly movable within a shuttle guide, on rotation of the actuator.

Ideally the shuttle screw threadingly engages the actuator. Preferably the thread has at least two starts. Ideally, the thread is a four start thread.

In one embodiment of the invention the actuator is a shuttle nut. Preferably the shuttle nut includes an operator handle. The operator handle may be a knurled portion of the shuttle nut.

In a particularly preferred arrangement the shuttle has at least two wings and the guide includes corresponding slots to substantially prevent rotation of the wings on rotation of the actuator. The oppositely directed wings have the effect of stabilising the shuttle in the guide slots.

A shuttle shaft preferably is connected to and extends forwardly of the shuttle. The shuttle shaft thereby provides an extension of the shuttle. Preferably the sheath is attached to the shuttle shaft.

The actuating means may comprise a threaded shaft and an associated thumbwheel which is rotated to move the shaft linearly. An anti-rotation means to control rotation of the threaded shaft is preferably provided. The thread on the shaft may be discontinuous. Ideally the thread is a multistart thread, preferably a four start thread.

In another arrangement the restraining sheath is slit helically at one or more circumferential location such that a combined linear and rotational motion of the sheath will maintain the opening for the guidewire to pass freely.

Preferably the stent deployment means is attached to the sheath. Typically, the actuating means includes a pull wire attached directly or indirectly to the sheath.

The invention also provides a constriction sheath for use with a delivery catheter of the invention. The constriction sheath has an opening which may be arranged

to align with the guidewire lumen entrance to prevent obstruction of the entrance on movement of the constriction sheath.

In a particularly preferred arrangement the opening is an elongate slot having a length which is greater than or equal to the length of a stent to be deployed.

The invention further provides a catheter for deploying a stent, the catheter having a pathway extending longitudinally and in parallel with a coaxial guidewire to permit free movement of the guidewire and providing a path for a stent release means.

Thus, the invention provides a means for rapidly deploying a self-expanding stent by way of a pull or push motion of the sheath without interference with any guidewire path.

The invention also provides a restraining sheath that is slit longitudinally at one or more circumferential location such that linear motion of the sheath will maintain the opening for the guidewire to pass freely.

The invention further provides a restraining sheath that is slit helically at one or more circumfrential location such that a combined linear and rotational motion of the sheath will maintain the opening for the guidewire to pass freely.

The invention further provides a rapid exchange stent delivery catheter having a pathway extending longitudinally and in parallel with a coaxial guidewire to permit movement of the guidewire and providing a path for a pull wire or suture used to release a stent restraining sheath.

Brief Description of the Drawings

The invention will be more clearly understood from the following description thereof given by way of example only in which :-

Fig. 1 is a perspective, partially cut-away view of part of a rapid exchange stent delivery catheter according to the invention;

Fig. 2 is an exploded view of the delivery catheter of Fig. 1;

Fig. 3 is a perspective, partially cut-away view of the delivery catheter;

Fig. 4 is a cross sectional view on the line IV– IV in Fig. 3;

Fig. 5 is a cross sectional view on the line V – V in Fig. 3.

Fig. 6 is a side cross sectional view of part of the catheter of Figs. 1 to 5;

Fig. 7(a) to 7(d) are diagrammatic views illustrating the delivery catheter of Figs 1 to 6, in use;

Figs 8(a) to 8(d) are views similar to Figs 7(a) to 7(d) with one stent deployment actuating mechanism;

Figs 9(a) to 9(d) are views similar to Figs 7(a) to 7(d) with another stent deployment actuating mechanism;

Fig. 10 is a perspective, partially cut-away cross sectional view of the stent deployment actuating mechanism of Fig. 8;

Fig. 11 is a plan cross sectional view of the actuating mechanism of Fig. 10;

Fig. 12 is a side elevational view of the actuating mechanism of Fig 10;

Figs 13 and 14 are side cross sectional views of the actuating mechanism of Fig 10 in different positions of use;

Fig. 15 is an exploded side view of a stent deployment system incorporating the actuating mechanism of Fig 10;

Fig. 16 is a plan view of a shuttle forming part of the actuating mechanism of Fig 10;

Fig. 17 is a side elevational view of the shuttle of Fig. 16;

Fig. 18 is an end view of the shuttle Figs 16 and 17;

Fig. 19 is a side elevational view of a shuttle nut forming part of the actuating mechanism of Fig 10;

Fig. 20 is a cross sectional view on the line XX-XX in Fig 19;

Fig. 21 is a plan view of a guide forming part of the actuating mechanism of Fig 10;

Fig. 22 is a diagrammatic exploded perspective view of one part of another actuating mechanism; and

Fig. 23 is a diagrammatic exploded perspective view of another part of the actuating mechanism of Fig 22.

Detailed Description

Referring to the drawings there is illustrated a rapid exchange stent delivery catheter 1 having a catheter shaft 2 defining a bore and a guidewire lumen 4 defined by a passageway having an entrance 5 and an exit 6. A guidewire 7 extends through the lumen 4. Around the lumen 4 a stepped recess 10 is provided for receiving a stent 11. The stent 11 is of a shape memory metallic alloy such as nitinol and is constrained in a pre-use constrained position by a sheath 20. The sheath 20 prevents the stent 11 from expanding until a desired location has been reached. By loading the distal end of the lumen over a guidewire 7 it is possible to advance the catheter to any desired position. The sheath 20 is then moved linearly by means of a stent deployment means to remove the constraint on the stent 11 and thereby allow it to be deployed by expanding into contact with a vessel wall 15 as illustrated in Figs. 7 to 9.

The sheath 20 is movable to deploy the stent 11 without obstructing the guidewire lumen entrance 5. An opening, in this case in the form of an elongate slot 25 is provided in the sheath 20 to align with the guidewire lumen entrance 5 so that the guidewire 7 is not obstructed during movement of the sheath 20 to deploy the stent 11. The slot 25 has a length which is greater than or equal to the length of the stent 11 to be deployed and a width which is at least the same size as, and preferably larger than, the guidewire 7 so that, on linear movement of the sheath 20, the guidewire entrance 5 is not interfered with.

Actuating means for moving the sheath 20 to deploy the stent 11 is preferably a linear actuating means. Referring to Figs 10 to 14 there is illustrated one such stent deployment/actuating mechanism. The mechanism is used to move a rod or pull wire 50 which is attached directly or indirectly to the sheath 20 by any suitable jointing means. For example, the sheath 20 may have its diameter reduced by way of a constraining shrink tube which may be shrunk onto either the rod 50 or alternatively onto an adhesive layer on the rod 50. Alternatively, a ring

bonded to sheath 20 may be attached to the rod 50 by welding, brazing or adhesive jointing.

The rod 50 is fixed to and extends from a shuttle shaft 51 which is movable on rotation of an operator handle defined by a knurled portion 52 of a shuttle nut 53. On rotation of the nut 53 the rod 50 is drawn inwardly from the extended position illustrated in Figs 10 to 13 to the retracted position illustrated in Fig. 14.

The shuttle shaft 51 is bonded to a shuttle 55 having a screw threaded portion 56 which screw threadingly engages a corresponding screw threaded portion 57 on the inner surface of the shuttle nut 53. The screw threaded portion 56 of the shuttle 55 is provided on two radially extending wings 58 which are located, on assembly, in corresponding opposed elongated slots 59 defined by elongate arms of a guide 60. The guide 60 has an end-cap forming end 61 which engages, on assembly in an outer body tube 62 of the mechanism. An opposite end of the assembly is closed by an end cap 65 which is a force fit in the barrel of the shuttle nut 53. Female luer connectors 70a, 70b are provided in the end cap 65 and in an elongated head portion 69 of the shuttle shaft 51 respectively.

The rod 50 has an inner core 80 which extends back through the actuating mechanism. The rod 50 which moves the sheath 20 is independently movable of the inner core 80. The rod 50 terminates in the head portion 69 of the shuttle shaft 51. The inner core 80 however continues back through the shuttle shaft 51, the inside of the shuttle 55, an inner tube 75 and is mounted to the rear end cap 65. The end cap 65 has a bore 81 in fluid communication with the luer connector 70a for flushing the inner core 80. The inner core 80 itself has two lumens and the second luer connector 70b provides a fluid connection for flushing. An O-ring 82 seals the annulus between the inner core 80 and the inner tube 75. Thus, the outer body of the rod 50 is isolated from the inner core 80.

In use, the side wings 58 of the shuttle 55 are trapped in the guide slots 59 of the guide 60 to prevent rotation of the shuttle 55 as the threads 56, 59 engage on rotation of the shuttle nut 53. Thus, the rotational motion of the shuttle nut 53 is converted into a linear movement of the shuttle 55 which in turn moves the shuttle shaft 51 and the rod 50, to which it is attached, linearly. This is most clearly illustrated in relation to the embodiment of Figs 22 and 23

The threading engagement between the threaded wings 58 of the shuttle 55 and the thread 57 inside the shuttle nut 53 provides ease of operation. A multi-start thread is desirable to allow linear actuation in a ratio suitable for the actuation handle in the clinical setting. The ratio of the number of turns to linear travel should be such that a stent of say 10 mm in length should not require excessive rotation. Using a single start thread would require a helix angle that could cause the rotator to bind up. The device is therefore preferably actuated by way of a two start thread as illustrated particularly in Figs 17 and 20. Even more desirably the device is actuated by way of a four start thread as illustrated in Figs 22 and 23. A thread with a number of starts is preferred as additional points of contact are provided for load sharing.

Referring particularly to Figs 9(a) to 9(d) in this example the linear actuating means comprises a threaded rod 40 rotatably engaged by a thumbwheel 41. The arrangement is such that on rotation of the thumbwheel 41, the rod 40 is moved linearly. An anti rotation pin 47 may be provided to prevent the rotation of the threaded rod during pull back of the sheath to release the stent 11. The rod 40 may be joined to a pull wire 45, for example, by brazing. The pull wire 45 may in turn be joined to the sheath 20 by any suitable jointing means. For example, the sheath 20 may have it's diameter reduced by way of a constraining shrink tube. This may be shrunk onto either the pull wire 45 or alternately onto an adhesive layer on the wire 45. Alternatively, a ring bonded to the sheath 20 may be attached to the pull wire 45 by welding, brazing or adhesive jointing.

It will be appreciated that the linear actuation mechanism may be attached to the sheath 20 at any point along its length. For example, the attachment may be distal to the guidewire entrance lumen, at or near the lumen or at or close to the proximal end.

It will also be appreciated that while a slot is shown as a preferred embodiment, any configuration of sheath that is not continuous in it's circumference could be used to achieve the end objective of having a method of attachment to the stent covering sheath. For example, the constriction means may be in the form of a curved wrap-around body, for example in the form of a helix or part thereof.

It will further be appreciated that the stent may be of any suitable size or shape and may be of any desired material of construction.

The invention is not limited to the embodiments hereinbefore described which may be varied in construction and detail.

CLAIMS

1. A rapid exchange stent delivery catheter for delivery and deployment of a stent comprising: -

an elongate catheter body;

a self-expanding stent overlying said catheter body at a distal end thereof;

a sheath overlying said stent to constrict the stent during delivery;

the catheter body having a guidewire lumen with a guidewire exit at a distal end of the catheter body and a guidewire entrance proximal of the stent;

a guidewire extending through the lumen between the guidewire entrance and the guidewire exit; and

stent deployment means comprising means for moving the sheath relative to the catheter body to release the stent;

the sheath having guidewire accommodating means for accommodating the guidewire so that the guidewire entrance is not obstructed during movement of the sheath relative to the catheter body.

2. A delivery catheter as claimed in claim 1 wherein the guidewire accommodating means is an opening in the sheath which is arranged to align with the guidewire entrance to prevent obstruction of the entrance on deployment of the stent.

3. A delivery catheter as claimed in claim 1 or 2 wherein the guidewire accommodating means is configured to correspond with the operation of the stent deployment means.

4. A delivery catheter as claimed in claim 2 or 3 wherein the sheath opening has a length which is greater than or equal to the length of the stent to be deployed.

5. A delivery catheter as claimed in claim 4 wherein the sheath opening comprises an elongate slot.

6. A delivery catheter as claimed in any preceding claim wherein the stent deployment means is a linear actuating means.

7. A delivery catheter as claimed in claim 6 wherein the actuating means includes converter means for converting rotational movement of an actuator into linear motion to move the sheath linearly.

8. A delivery catheter as claimed in claim 7 wherein the converter means comprises a shuttle which is linearly movable within a shuttle guide on rotation of the actuator.

9. A delivery catheter as claimed in claim 8 wherein the shuttle screw threadingly engages the actuator.

10. A delivery catheter as claimed in claim 9 wherein the thread has at least two starts.

11. A delivery catheter as claimed in claim 10 wherein the thread is a four start thread.

12. A delivery catheter as claimed in any of claims 7 to 11 wherein the actuator is a shuttle nut.

13. A delivery catheter as claimed in claim 12 wherein the shuttle nut includes an operator handle.

14. A delivery catheter as claimed in claim 13 wherein the operator handle is a knurled portion of the shuttle nut.

15. A delivery catheter as claimed in any of claims 8 to 14 wherein the shuttle has at least two wings and the guide includes corresponding slots to substantially prevent rotation of the wings on rotation of the actuator.

16. A delivery catheter as claimed in any of claims 8 to 15 wherein a shuttle shaft is connected to and extends forwardly of the shuttle.

17. A delivery catheter as claimed in claim 16 wherein the sheath is attached to the shuttle shaft.

18. A delivery catheter as claimed in claim 6 wherein the actuating means comprises a threaded shaft and an associated thumbwheel which is rotated to move the shaft linearly.

19. A delivery catheter as claimed in claim 18 including an anti-rotation means to control rotation of the threaded shaft.

20. A delivery catheter as claimed in claim 18 or 19 wherein the thread on the shaft is discontinuous.

21. A delivery catheter as claimed in any of claim 18 to 21 wherein the thread is a multistart thread.

22. A delivery catheter as claimed in claim 21 wherein the thread is a four start thread.

23. A delivery catheter as claimed in any of claims 1 to 4 wherein the restraining sheath is slit helically at one or more circumferential location such that a combined linear and rotational motion of the sheath maintains the opening for the guidewire to pass freely.

24. A delivery catheter as claimed in any preceding claim wherein the stent deployment means is attached to the sheath.

25. A delivery catheter as claimed in claim 24 wherein the stent deployment means comprises a pull wire attached directly or indirectly to the sheath.

26. A rapid exchange stent delivery catheter substantially as hereinbefore described with reference to the accompanying drawings.

27. A sheath for use with a delivery catheter of any preceding claim, the sheath having an opening which is arranged to align with the guidewire entrance to prevent obstruction of the entrance on movement of the stent.

28. A constriction sheath as claimed in claim 27 wherein the opening has a length which is greater than or equal to the length of a stent.

29. A sheath as claimed in claim 28 wherein the opening is an elongate slot.

30. A sheath as claimed in claim 27 or 28, the sheath being slit helically at one or more circumferential locations such that a combined linear and

rotational motion of the sheath will maintain the opening for the guidewire to pass freely.

31. A rapid exchange stent delivery catheter having a pathway extending longitudinally and in parallel with a coaxial guidewire to permit free movement of the guidewire and release of a stent restraining sheath.

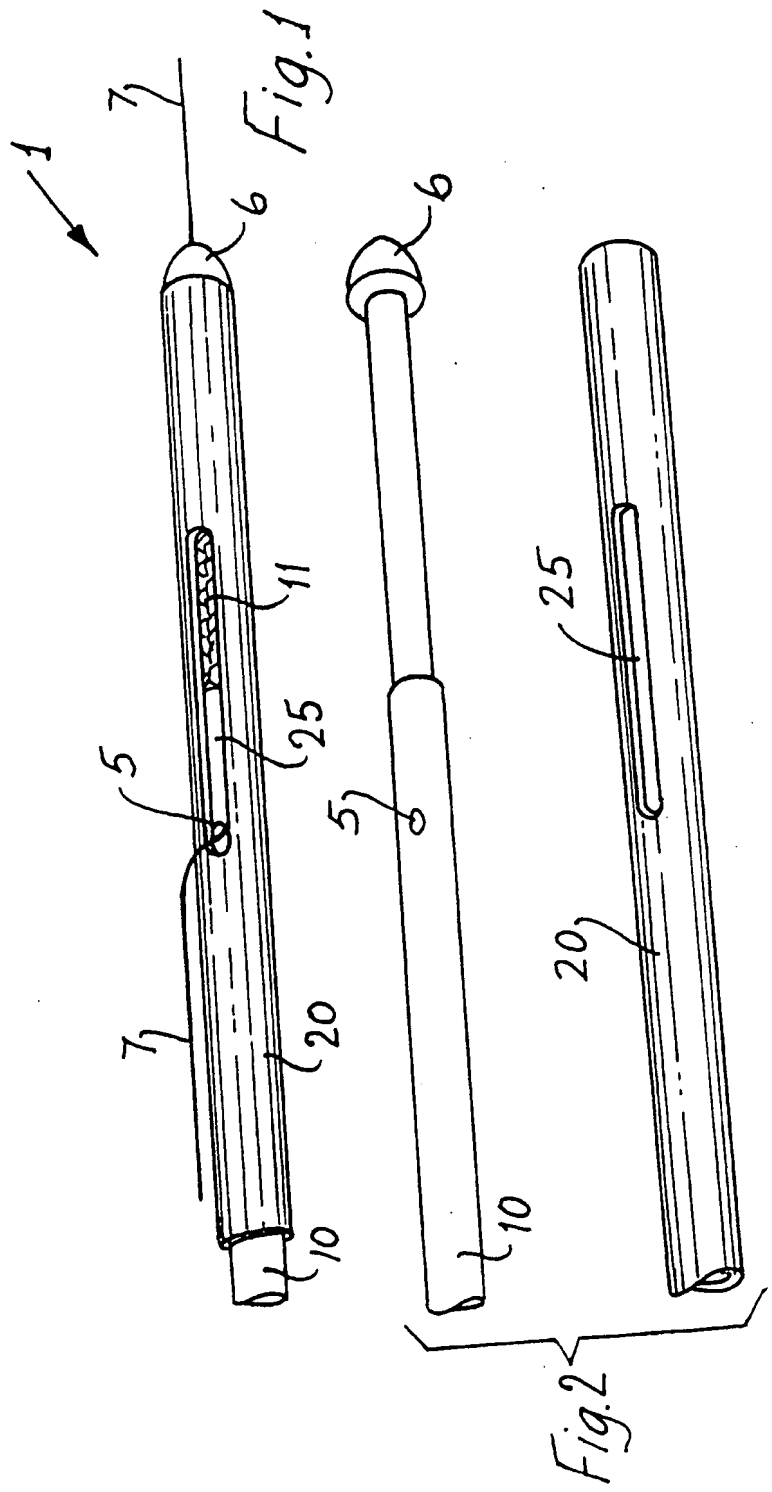


Fig.1

Fig.2

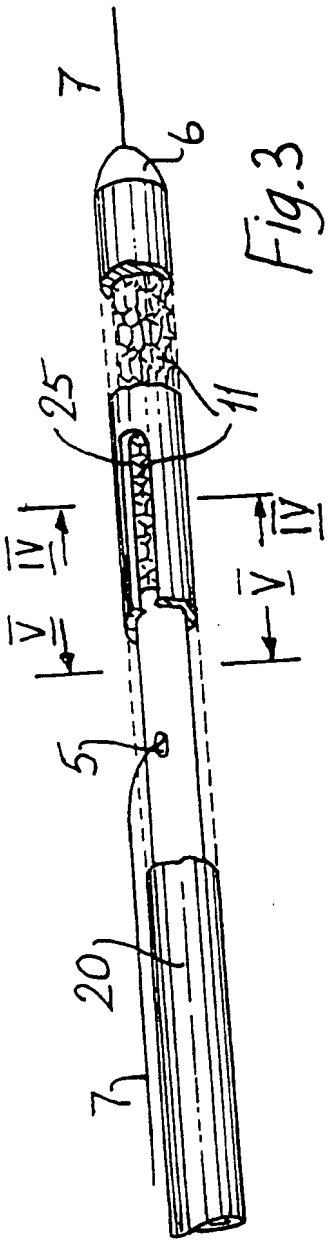


Fig.3

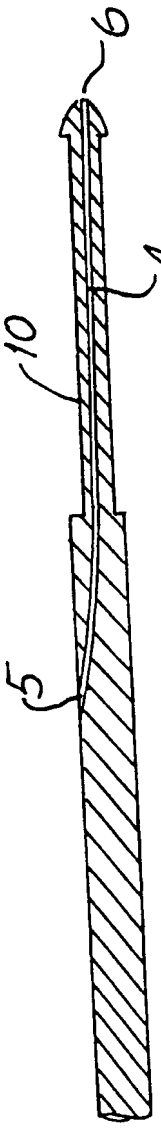


Fig.6

Fig.5

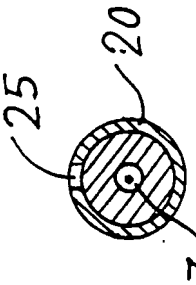


Fig.4

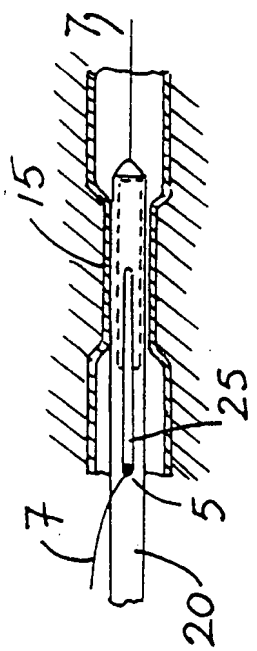


Fig. 7(a)

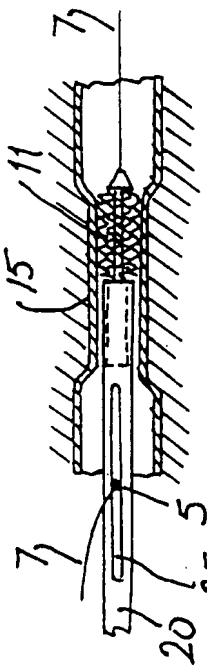


Fig. 7(b)

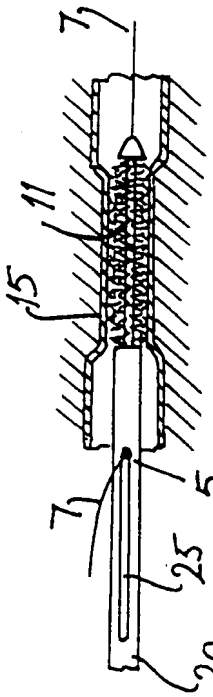


Fig. 7(c)

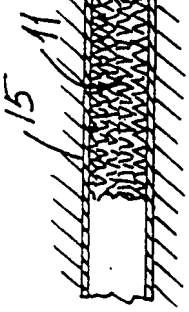


Fig. 7(d)

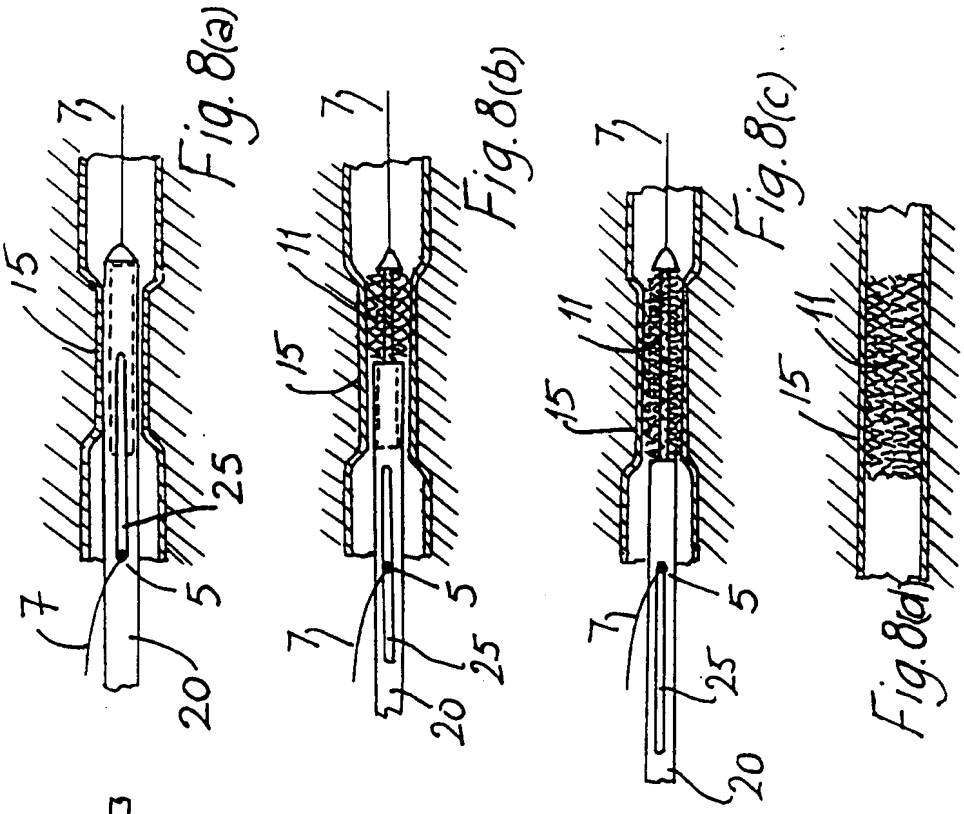
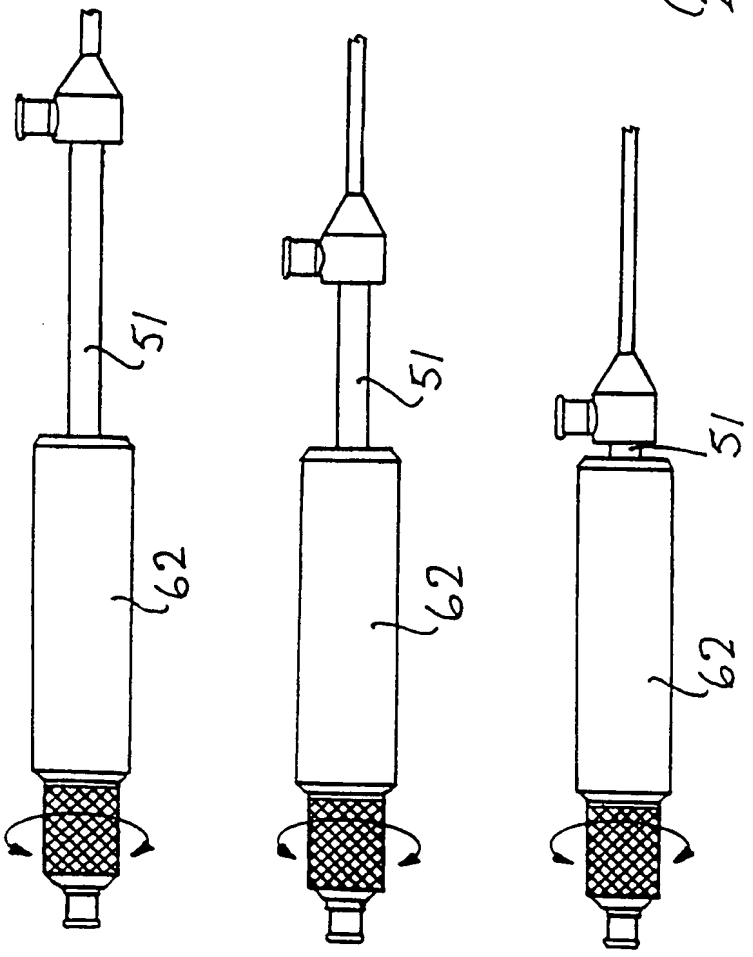


Fig. 8(a)
Fig. 8(b)
Fig. 8(c)
Fig. 8(d)
7
15
11
25
5
20


51
62

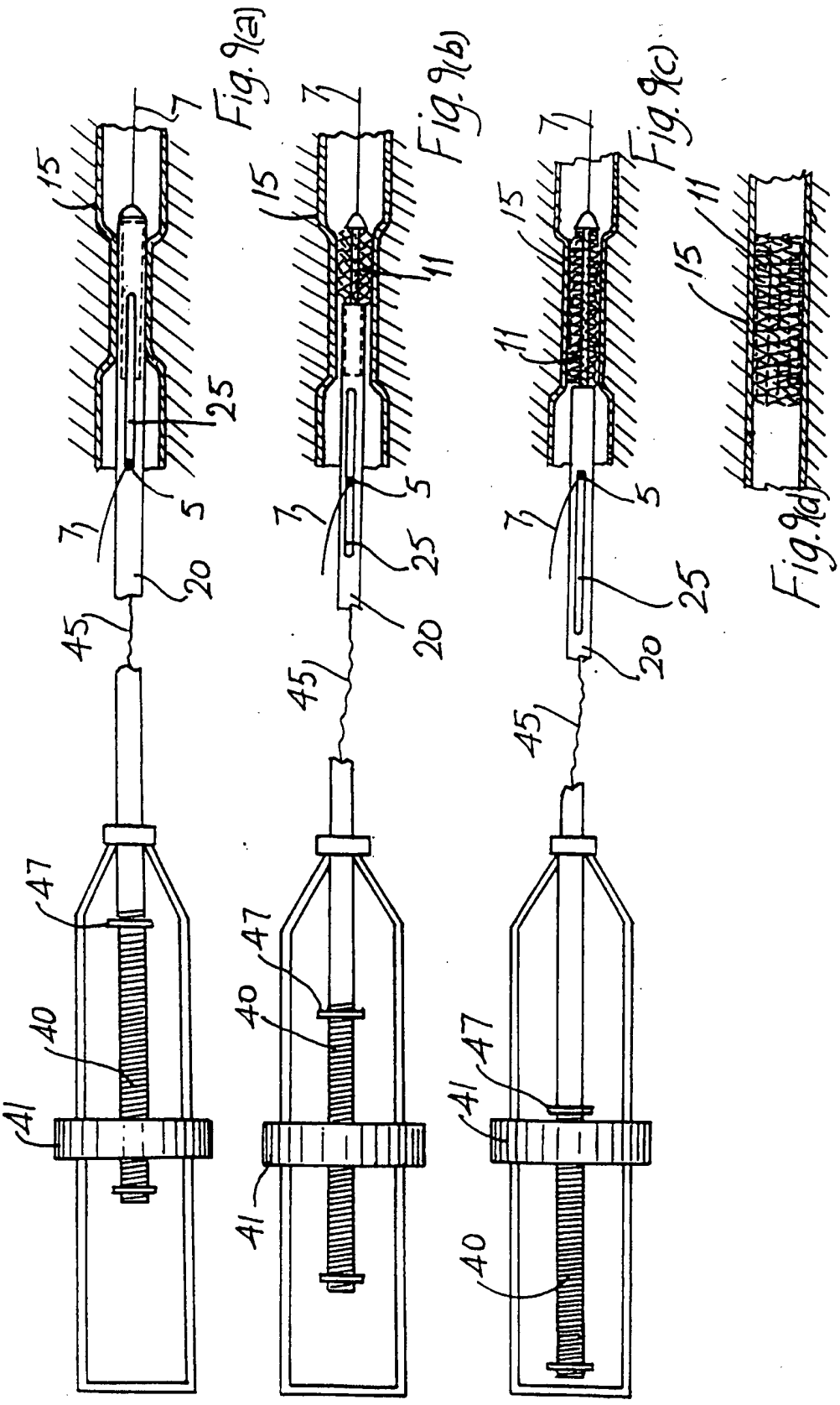


Fig. 9(a)
Fig. 9(b)
Fig. 9(c)
Fig. 9(d)
15
7
25
5
20
45
47
40
41
11

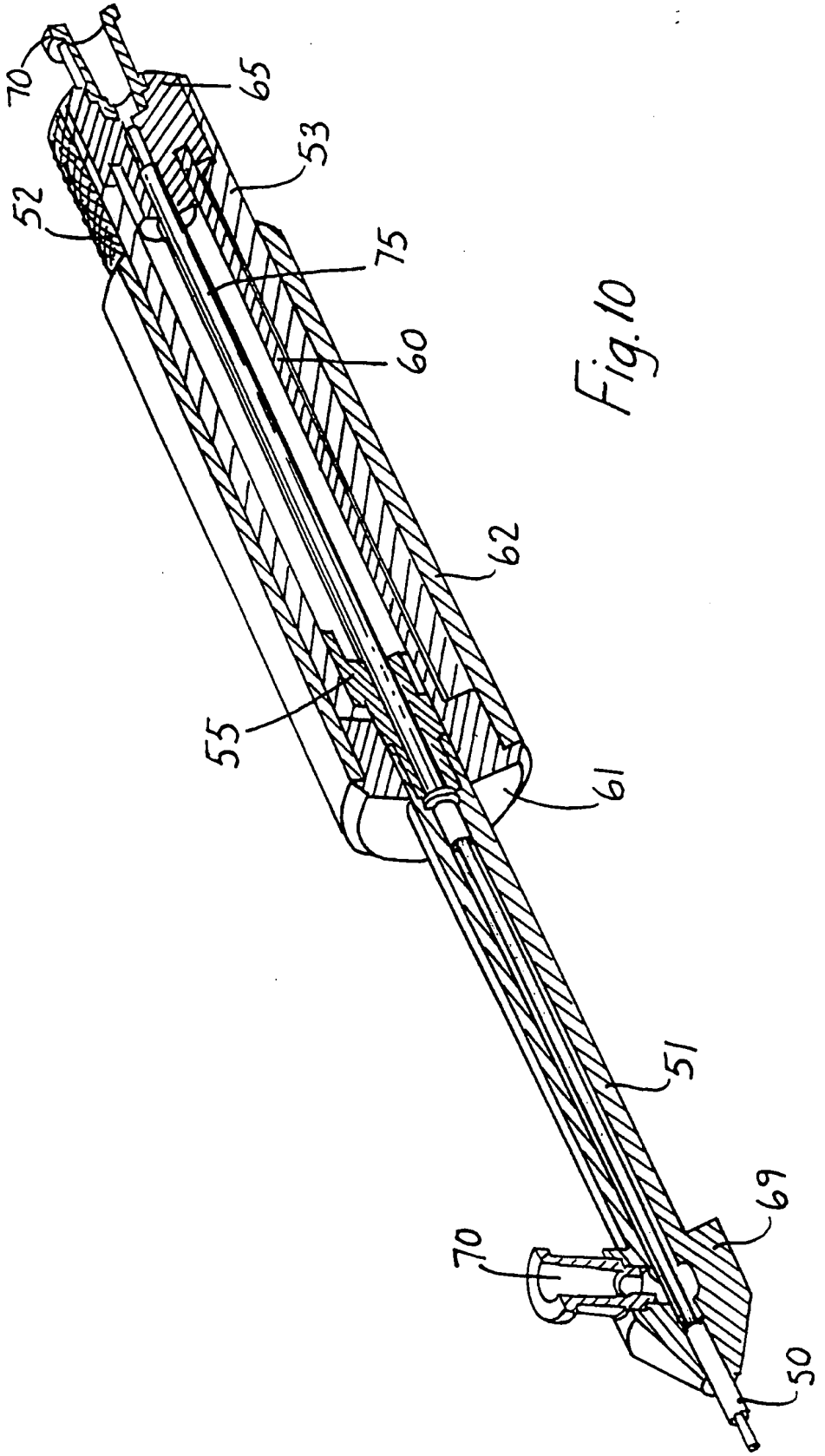


Fig. 10

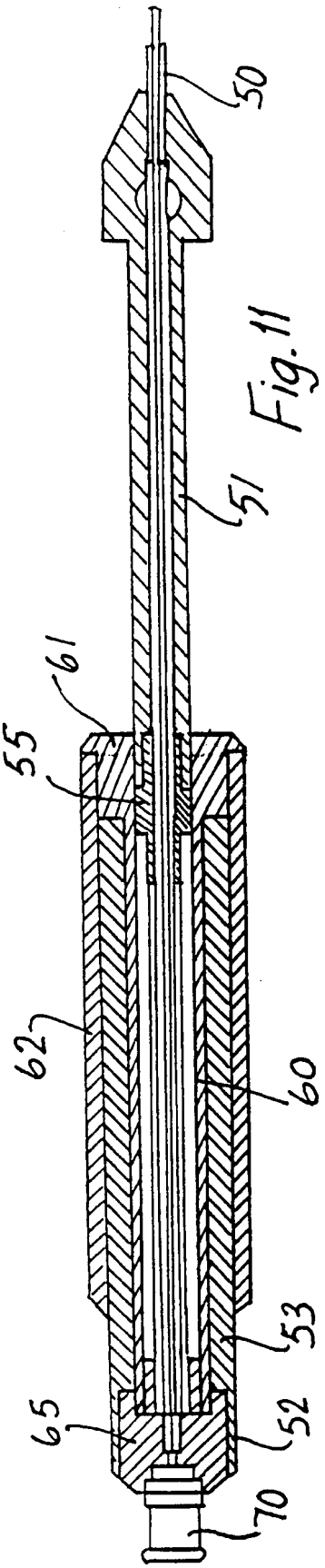


Fig. 11

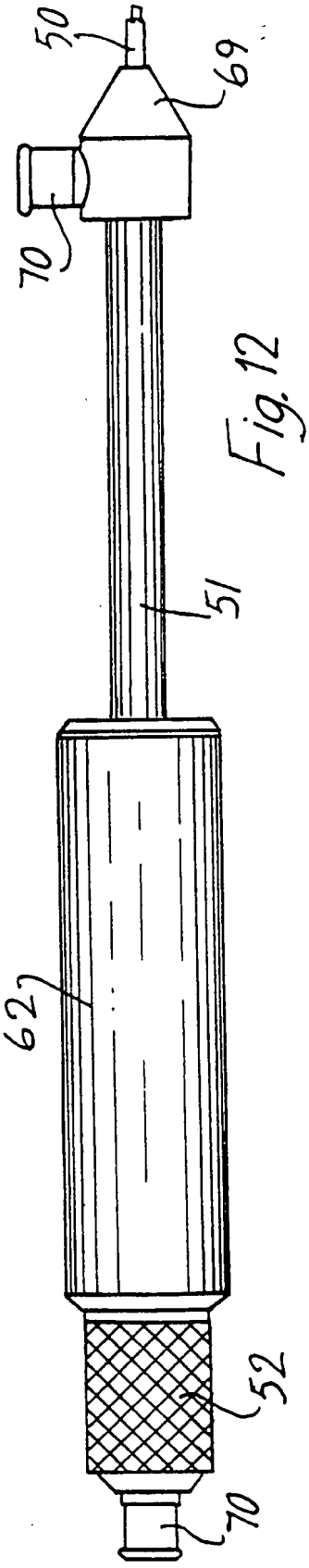


Fig. 12

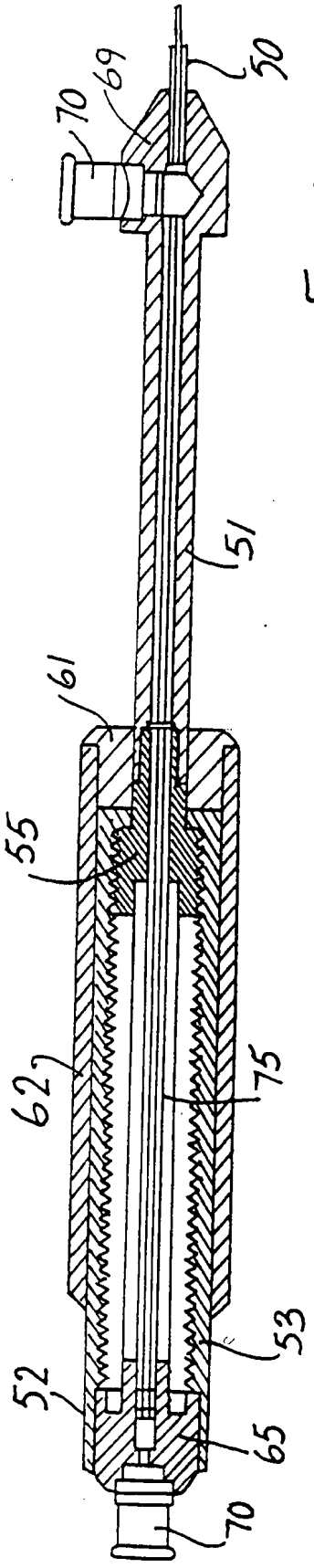


Fig. 13

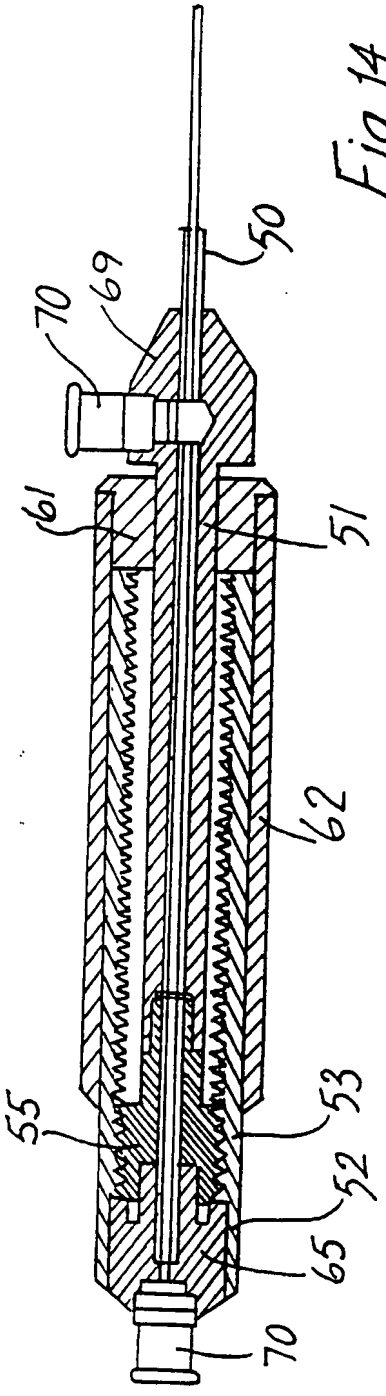


Fig. 14

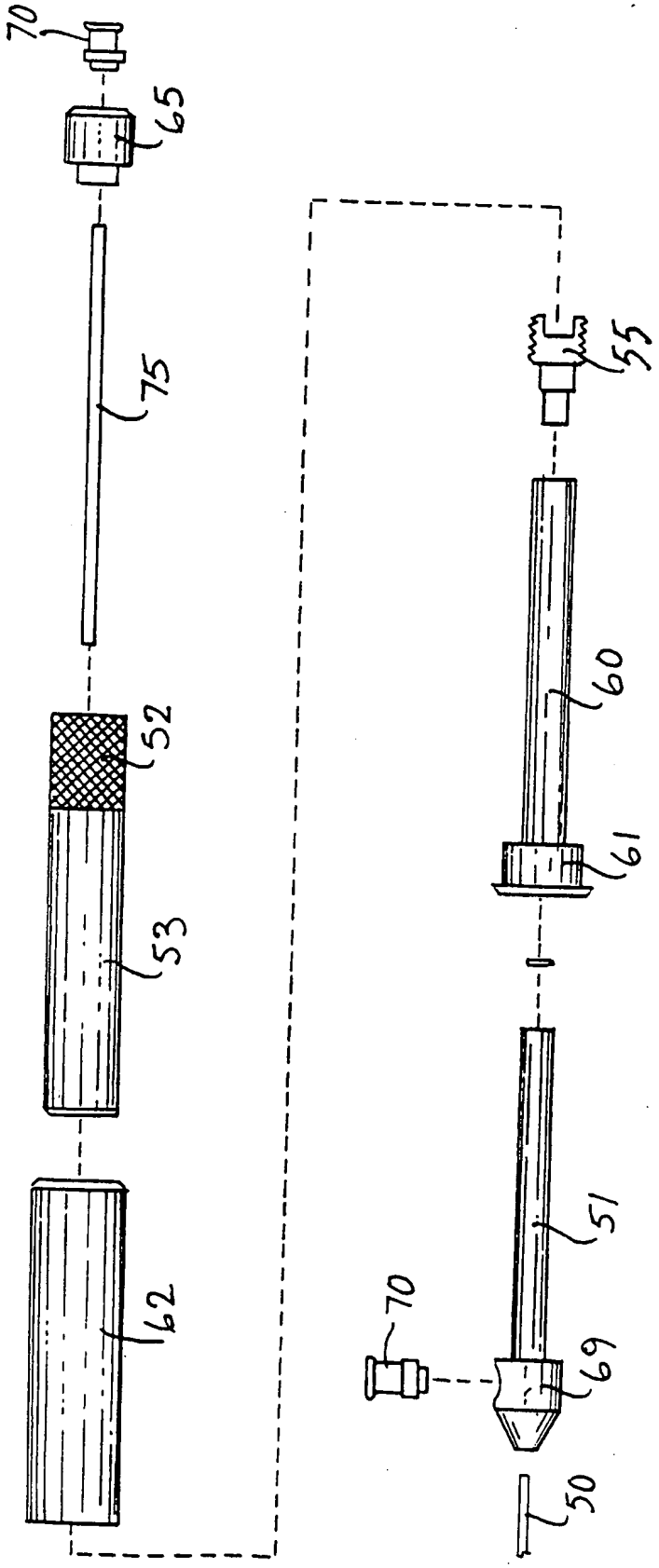


Fig. 15

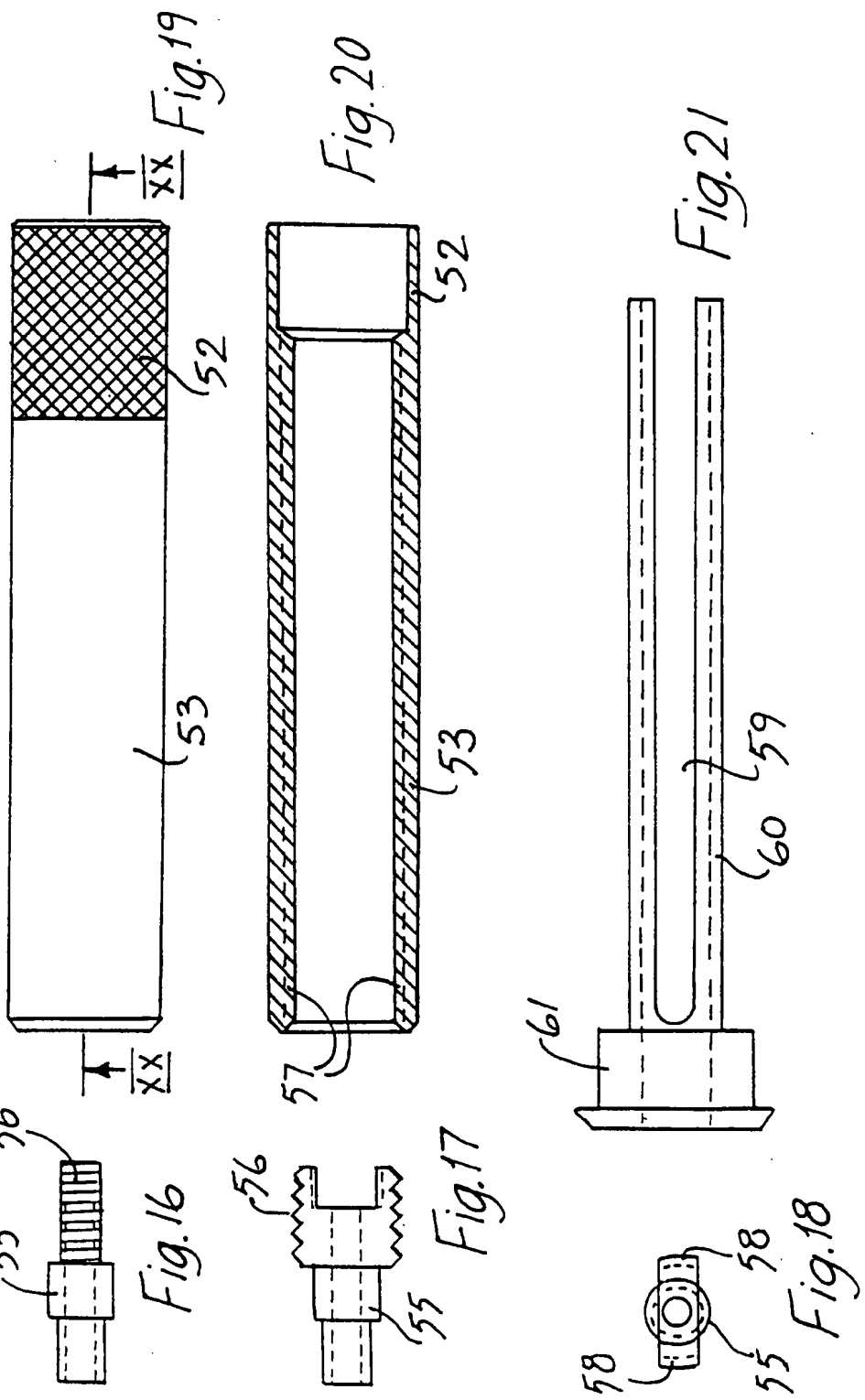


Fig.19 Fig.20 Fig.21

Fig.16 Fig.17 Fig.18

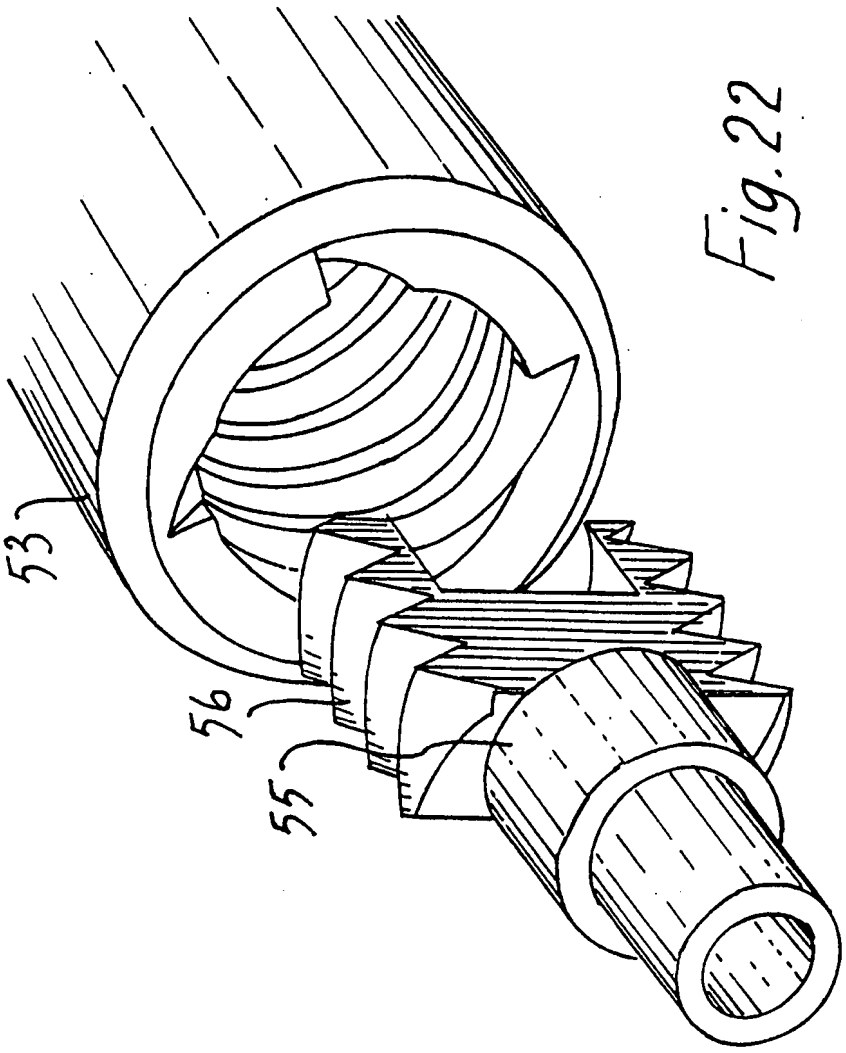


Fig. 22

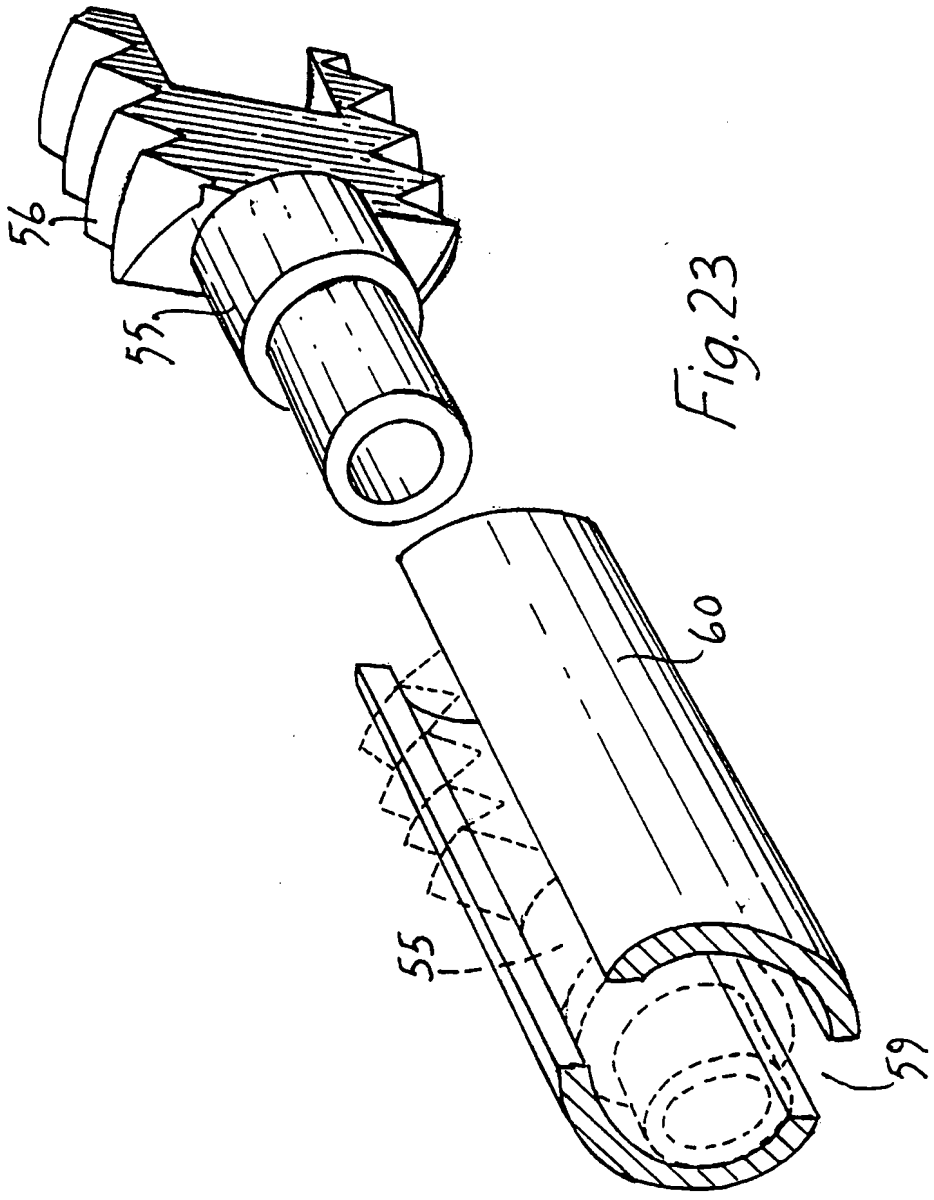


Fig. 23

INTERNATIONAL SEARCH REPORT

Internal Application No
PCT/IE 99/00018

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 819 411 A (ADVANCED CARDIOVASCULAR SYSTEMS, INC.) 21 January 1998 (1998-01-21)	1-6,24, 27-29,31
Y	column 7, line 48 - column 8, line 18; figures 11-13	7-9,12, 13,16-18
Y	EP 0 536 610 A (ANGIOMED AG) 14 April 1993 (1993-04-14) column 6, line 28 - column 9, line 1; figures 1-6	7-9,12, 13,16-18

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 August 1999	19. 08. 1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Smith, C

3

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inte .ional application No.
PCT/IE 99/00018

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 26
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 26

Rule 6.2(a) PCT.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internal Application No
PCT/IE 99/00018

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 819411 A	21-01-1998	CA 2198530 A	16-01-1998
		JP 10057502 A	03-03-1998
EP 536610 A	14-04-1993	DE 4133696 A	15-04-1993
		DE 4207557 A	16-09-1993
		AT 157525 T	15-09-1997
		DE 59208848 D	09-10-1997
		ES 2109969 T	01-02-1998
		JP 5200121 A	10-08-1993
		US 5433723 A	18-07-1995